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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,412	04/26/2006	Michael Anthony Harris	PB60562USw	4137

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EXAMINER	
MOORE, SUSANNA	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
04/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/577,412	HARRIS ET AL.	
	Examiner	Art Unit	
	SUSANNA MOORE	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

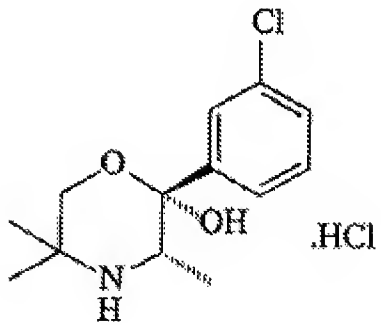
1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is in response to an Application filed, 4/26/2006, with a preliminary amendment. There are 16 claims pending and 16 under consideration. Claims 1-16 are drawn to a process of preparing a salt of (+)-(2S, 3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2- morpholinol. This is the first action on the merits.

Specification

The abstract of the disclosure is objected to because the abstract is too vague. The abstract should provide a short summary of the invention. The Examiner suggests using claim 1 with the structure for the abstract. Correction is required. See MPEP § 608.01(b).



Information Disclosure Statement

The information disclosure statement (IDS) submitted on 4/26/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. There are two references which may have been misplaced. Applicant may resubmit the references for consideration.

Claim Objections

Claims 1, 2, 5, 6 and 15 are objected to because of the following informalities: the abbreviation/acronym, "L-DTTA" should be spelled-out followed by the abbreviation/acronym in parenthesis. Appropriate correction is required.

Claims 2 and 14 are objected to because of the following informalities: there is a circle between the lines of the claims. Appropriate correction is required.

Claims 5 is objected to because of the following informalities: the term "claim: is repeated in said claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fang et al. (US 20020052341 A1).

The instant Application is drawn to a process of preparing (+)-(2S, 3S)-2-(3-chlorophenyl)-3,5,5- trimethyl-2-morpholinol that comprises mixing

i) a sample **comprising** (-)-(2R, 3R)-2-(3-chlorophenyl)-3,5,5- trimethyl-2-morpholinol ((2R, 3R) enantiomer),

ii) at least one solvent (ethyl acetate) having a boiling point of at least 50°C and

iii) 1.1 equivalent or higher of L-DTTA in any order, heating the mixture to at least 50°C for at least 1 hour to form crystals comprising an L-DTTA salt of (+)-(2S, 3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol ((2S, 3S) enantiomer), and isolating the crystals, wherein the yield of the L-DTTA salt of the (2S, 3S) enantiomer is greater than 50% based on said sample.

Furthermore, claim 9 is drawn to a continuous process and claim 14 is drawn to the process of claim 1, wherein said sample comprising the (2R, 3R) enantiomer is formed in a step

comprising reacting 2-bromo-3'-chloropropiophenone with 2-amino-2-methylpropanol. Moreover, claims 15 and 16 is drawn to converting the L-DTTA salt to another salt (HCl).

Fang et. al. teaches the a process of preparing (+)-(2S, 3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol by mixing

i) a racemic mixture of 2-(3-chlorophenyl)-3,5,5- trimethyl-2-morpholinol which contains the (2R, 3R) enantiomer,

ii) at least one solvent (ethyl acetate) having a boiling point of at least 50°C and

iii) 1.0 equivalent of L-DTTA, heating the mixture to reflux for 10-30 minutes to form crystals comprising an L-DTTA salt of (+)-(2S, 3S)-2-(3- chlorophenyl)-3,5,5-trimethyl-2-morpholinol ((2S, 3S) enantiomer), and isolating the crystals, wherein the yield of the L-DTTA salt of the (2S, 3S) enantiomer is greater than 47% based on said sample, 91% e.e., **see page 15, paragraphs 0129-0130.**

The only difference between the reference and the is:

a) a 1.0 versus Applicant's 1.1 equivalent of L-DTTA is used;

b) 10-30 minutes versus Applicant's at least 1 hour under reflux; and

c) a 47% versus Applicant's greater than 50% yield of the L-DTTA is obtained.

The adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

The continuous process in nothing more than an optimization recrystallization technique. The process outlined in claim 14 can be found in paragraphs 0126 and 0127, where a synthetic step comprising reacting 2-bromo-3'-chloropropiophenone with 2-amino-2-methylpropanol can be found. Moreover, paragraphs 0135 and 0138 embrace converting the L-DTTA salt to another salt (HCl).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6274579. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no patentable distinction between compounds, compositions of said compounds, methods of intended use of said compounds and a process of making said compounds. Furthermore, there was no restriction requirement in either case.

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6391875. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no patentable distinction between methods of intended use or a process of making (+)-(2S, 3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2- morpholinol. Furthermore, there was no restriction requirement in either case.

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6734213. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no patentable distinction between methods of intended use or a process of making (+)-(2S,

3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2- morpholinol. Furthermore, there was no restriction requirement in either case.

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6998400. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no patentable distinction between methods of intended use or a process of making (+)-(2S, 3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2- morpholinol. Furthermore, there was no restriction requirement in either case.

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6855820. Although the conflicting claims are not identical, they are not patentably distinct from each other because the process described in the '820 patent is embraced by the instant process. The dependent claims in each application are drawn to limitations which are considered customary for separating enantiomers by recrystallization techniques, which render the instant application obvious.

Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10577172. Although the conflicting claims are not identical, they are not patentably distinct from each other because the process described in the '172 Application is embraced by the instant Application. The '172 process embraces the process for preparing (+)-(2S, 3S)-2-(3-chlorophenyl)-3,5,5- trimethyl-2-morpholinol in its free base, its salt form, or both, which process comprises a dynamic kinetic resolution by equilibrating the two chiral centers of (+/-)-

(2R*, 3R*)-2-(3-chlorophenyl)-3,5,5-trimethyl-2- morpholinol. The instant Application is drawn to a process of preparing (+)-(2S, 3S)-2-(3-chlorophenyl)-3,5,5- trimethyl-2-morpholinol which uses the language "comprises" which embraces dynamic kinetic resolution with a base as described in the '172 Application. The dependent claims in the '172 Application further describe bases and other chiral salts which are known in the art as common chiral resolution salts. Furthermore, the dependent claims in each application are drawn to limitations which are considered customary for separating enantiomers by recrystallization techniques, which render the instant application obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No obviousness-type double patenting rejections over applications 10944814, 10577417, 10577410, 11407192 and 10944814 are being made because all of the cases except 10577417 are abandoned. The process described in the '417 application is patentably distinct from the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624